

Exhibit B

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS

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4 UNITED STATES OF AMERICA,
5 Plaintiff,

6 V. Criminal Action No. 05-10282-RCL

7 SERONO LABORATORIES, INC., December 15, 2005, 10:31 a.m.
8 Defendant. Boston, Massachusetts
9 _____

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12 TRANSCRIPT OF PLEA/SENTENCING OF SERONO LABORATORIES, INC.

13 BEFORE THE HONORABLE REGINALD C. LINDSAY

14 UNITED STATES DISTRICT COURT
15 JOHN J. MOAKLEY U.S. COURTHOUSE
16 ONE COURTHOUSE WAY
17 BOSTON, MA 02210
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22 DEBRA M. JOYCE, RMR, CRR
23 Official Court Reporter
24 John J. Moakley U.S. Courthouse
25 1 Courthouse Way, Room 5204
Boston, MA 02210
617-737-4410

1 APPEARANCES:

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P R O C E E D I N G S

(The following proceedings were held in open court before the Honorable Reginald C. Lindsay, United States District Judge, United States District Court, District of Massachusetts, at the John J. Moakley United States Courthouse, 1 Courthouse Way, Boston, Massachusetts, on December 15,, 2005.

The defendant, Serono Laboratories, Inc., is present with counsel. The Assistant United States Attorney is present.)

THE CLERK: This is criminal action 05-10282, United States v. Serono Labs.

Would counsel please state your name for the record?

MS. CARMODY: Good morning, your Honor. Mary Elizabeth Carmody the United States.

MS. MILLS: Sondra Mills for the United States.

THE COURT: Good morning.

MR. DEPIPPPO: Henry Depippo for Serono Labs.

MS. TEARNEY: Melissa Tearney for Serono Labs.

MR. DEPIPPPO: With us is corporate representative Tom Gunning.

THE COURT: Would you, sir, give me your name?

MR. DEPIPPPO: Henry Depippo.

THE COURT: And you, ma'am?

MS. TEARNEY: Melissa Tearney.

1 THE COURT: And the gentleman between the two of
2 you once again?

3 MR. GUNNING: It's Tom Gunning.

4 THE COURT: Okay. Thank you.

5 Ladies and gentlemen, let me first begin by
6 apologizing for the late start of this morning's proceedings.
7 This is not my customary courtroom. I'm usually sitting next
8 door in courtroom 11, and some work is being done in courtroom
9 11 to enable me to have all the fancy electronic equipment that
10 you see in this courtroom starting Monday morning, and in order
11 for that to work Monday morning, I had to be trained -- and I
12 put that in quotation marks -- on the system this morning. And
13 so I was finishing my training. By the way, when I put
14 training in quotation marks, that is no reflection on the
15 trainer, but rather on the trainee. And so I was learning how
16 that system worked or attempting to learn how that system
17 worked, and so I am later than I anticipated.

18 But I'm here, and we are here this morning for what
19 I understand to be a plea of the defendant Serono Labs,
20 Incorporated; and then, as I understand it, we will proceed to
21 the sentencing if the plea is done. Is that right,
22 Mr. Depippo?

23 MR. DEPIPPPO: Yes, your Honor.

24 THE COURT: Let me suggest to you that in the
25 ordinary case in which there is a preplea presentence report

1 prepared in anticipation that the sentencing would immediately
2 follow the plea, that generally is what happens. There's a
3 plea, I decide whether I can accept the plea, and then we go on
4 to the sentence.

5 This plea, I understand, is being tendered pursuant
6 to Rule 11(c)(1)(e), Federal Rules of Criminal Procedure. It
7 is, therefore, a so-called or often called binding plea, which
8 I understand to mean that the plea may be withdrawn by the
9 defendant if I do not accept the terms of the plea; is that
10 right?

11 MR. DEIPPO: Yes, your Honor.

12 THE COURT: So I think that the most efficient way
13 for me to proceed this morning is to do much of what I would do
14 in a sentencing as I take the plea. So I'm going to combine
15 the sentencing with the plea.

16 I have some questions, which I might ask during the
17 course of this plea. They are relevant to the plea, and they
18 would be relevant to sentencing as well. So I anticipate that
19 I will do it that way.

20 Is that satisfactory to everyone?

21 MS. CARMODY: Yes, your Honor.

22 THE COURT: Okay.

23 All right. I was looking for some notes and papers
24 that I made in connection with this matter.

25 Mr. Depippo, is Mr. Gunning the corporate officer

1 who will be representing the defendant this morning?

2 MR. DEIPPPO: Yes, your Honor, he is.

3 THE COURT: All right. Mr. Gunning, could you
4 stand a minute, please?

5 I think I will have you sworn right now, all right?

6 THE CLERK: If you can please raise your right
7 hand.

8 (Tom Gunning was sworn in by the Clerk.)

9 THE COURT: Would you state your name, please?

10 MR. GUNNING: It's Tom Gunning.

11 THE COURT: And do you hold a corporate office in
12 the defendant Serono Laboratories, Incorporated?

13 MR. GUNNING: I do.

14 THE COURT: What office do you hold?

15 MR. GUNNING: Vice president and general counsel.

16 THE COURT: Let me tell you, Mr. Gunning, what we
17 are going to do this morning. I understand that the
18 corporation has agreed, and I see papers -- a resolution of the
19 corporation --

20 MR. GUNNING: Yes.

21 THE COURT: -- that it will waive indictment in
22 this matter and plead guilty thereafter to an information of
23 the United States attorney. And I have to be satisfied that
24 the waiver of indictment is voluntarily and knowingly given, so
25 I have to find out how much you know about it, since you

1 represent the corporation. And if I accept the waiver of
2 indictment, then we can move to the plea.

3 You're now under oath, I will be asking you some
4 questions or giving you some information to make sure that
5 you -- and by you in this context I mean the corporation --
6 will understand -- understands the consent of waiving
7 indictment and the concept of pleading guilty to an
8 information.

9 Because you are under oath, you are required to
10 answer all of my questions truthfully. If you fail to answer
11 any question truthfully, you personally may be subject to other
12 penalties growing out of offenses against the United States,
13 like making false statements and perjury. And you may also,
14 since you represent the company, subject the company, the
15 corporation to those offenses as well. Do you understand?

16 MR. GUNNING: I understand.

17 THE COURT: All right. Do you have any question
18 before we begin?

19 MR. GUNNING: No.

20 THE COURT: All right. You are the vice president
21 and general counsel of the corporation, the defendant in this
22 case you have told me; is that correct?

23 MR. GUNNING: Yes.

24 THE COURT: All right. The corporation is aware,
25 that is, you are aware that the corporation has been charged

1 with two separate felonies, one of them is a conspiracy to
2 introduce into interstate commerce, with intent to defraud,
3 certain adulterated, mislabeled medical devices; and the second
4 felony with which the corporation is charged is conspiracy to
5 offer to pay illegal remuneration. Do you understand that?

6 MR. GUNNING: Yes, sir.

7 THE COURT: A felony offense, Mr. Gunning, is an
8 offense against the United States which, were there an
9 individual, there would a term of imprisonment greater than one
10 year. And no one, including a corporation, may be prosecuted
11 and tried for a felony in this court, except upon indictment by
12 a grand jury. Do you understand?

13 MR. GUNNING: I do.

14 THE COURT: On the other hand, the right to
15 indictment by grand jury may be waived by the defendant, and it
16 is my understanding that this defendant intends to waive
17 indictment by the grand jury.

18 Before that happens, I want the corporation to
19 understand that it has a constitutional right to an indictment
20 before these charges may be prosecuted. And unless the
21 corporation waives indictment, the case may not proceed.

22 If the corporation does not waive indictment, the
23 United States attorney may present this case to a grand jury
24 and ask of a grand jury indict the corporation. A grand jury
25 is composed of at least 16 and not more than 23 persons. Those

1 persons would be drawn at random from among the population
2 residing in the eastern division of the District of
3 Massachusetts. The eastern division of the District of
4 Massachusetts comprises all of those counties east of Worcester
5 County.

6 If the case were to go to a grand jury, at least 12
7 of them would have to find that there is probable cause to
8 believe that the felonies charged in this case were committed
9 and that the corporation committed those felonies. And you
10 should understand, if the case were presented to a grand jury,
11 the grand jury might indict the corporation, it might not
12 indict the corporation. Do you understand?

13 MR. GUNNING: I do.

14 THE COURT: Now, if the corporation waives
15 indictment, the case will proceed against the corporation as if
16 there had been an indictment. Do you understand that?

17 MR. GUNNING: Yes.

18 THE COURT: Has the corporation discussed the
19 matter of waiving indictment with its counsel?

20 MR. GUNNING: Yes.

21 THE COURT: And does the corporation understand the
22 right to an indictment?

23 MR. GUNNING: Yes.

24 THE COURT: Have any threats or promises been made
25 to the corporation apart from what's in the settlement

1 agreement, the plea agreement in this case to induce the
2 corporation to waive indictment?

3 MR. GUNNING: No.

4 THE COURT: Does the corporation wish to waive
5 indictment?

6 MR. GUNNING: Yes.

7 THE COURT: Mr. Depippo, do you see any reason why
8 the corporation should not waive indictment?

9 MR. DEPIPPPO: No, your Honor.

10 THE COURT: Ms. Carmody, are you the right person
11 to ask? Does the government see any reason why the corporation
12 should not waive indictment?

13 MS. CARMODY: No, your Honor.

14 THE COURT: Is there a written waiver of indictment
15 signed by Mr. Gunning as the authorized corporate
16 representative?

17 MS. TEARNEY: We have it with us and we'll sign
18 it. We didn't know if it needed to be signed in front of a
19 judicial officer.

20 THE COURT: The corporation has authorized you, has
21 it not, to sign this waiver of indictment on its behalf?

22 MR. GUNNING: It has.

23 THE COURT: All right. I have been handed a
24 document called waiver of indictment in the case of United
25 States of America v. Serono Laboratories, Incorporated,

1 criminal action 05-10282-RCL.

2 Mr. Gunning has executed this document in my
3 presence. It is co-signed -- co-signed is not the right
4 word -- but witnessed by Melissa Tearney, Esq., counsel for the
5 defendant.

6 I find that the waiver is knowingly and voluntarily
7 made, and I, therefore, accept it; and I will execute the
8 waiver indicating my acceptance of it.

9 Now I want to proceed to the plea phase. As I
10 said, part of what we are going to be doing in the plea phase
11 is also relevant to what will happen during the sentencing
12 phase.

13 You are, Mr. Gunning, authorized by the corporation
14 to enter a plea of guilty to these two felonies, are you not?

15 MR. GUNNING: Yes.

16 THE COURT: And you understand from our earlier
17 conversation what it is the corporation has been charged with;
18 is that right?

19 MR. GUNNING: I do.

20 THE COURT: All right.

21 Just so the record is clear, let me state, again,
22 the corporation has been charged in count one with a violation
23 of Title 18 United States Code section 371, the conspiracy
24 statute; and the conspiracy that's charged in that is a
25 conspiracy to introduce into interstate commerce, with intent

1 to defraud and mislead, adulterated medical devices.

2 Count two also charges a conspiracy pursuant to
3 Title 18 United States Code section 371. The conspiracy there
4 charged is conspiracy to offer to pay illegal remuneration to
5 health care providers.

6 I may have side the indictment charges. The
7 information charges. We're proceeding now by information of
8 the United States attorney.

9 Mr. Gunning, let me advise the corporation through
10 you that the corporation faces, if it pleads guilty to these
11 felonies, maximum penalties as follows: A term of probation of
12 five years; a fine of \$228,224 -- \$228 million, excuse me,
13 \$228,244,000.

14 PROBATION OFFICER: 224. The second figure is 224,
15 Judge.

16 THE COURT: Let me try it again. \$228,224,000,
17 with respect to count one, and a special assessment of \$400.

18 With respect to count two, the corporation --

19 PROBATION OFFICER: Excuse me, Judge, that's
20 actually the total fine.

21 THE COURT: I'm sorry. I don't do corporations
22 that often, so I'm having my probation officer sit next to me
23 and make sure I say all of this correctly.

24 All right. Let me start again, Mr. Gunning.

25 On count one, the corporation faces a maximum term

1 of probation of five years; and on count two, the corporation,
2 likewise, faces a maximum term of five years.

3 And in addition, the corporation faces a maximum
4 fine on both of the counts of \$228,224 --

5 PROBATION OFFICER: I'm sorry, Judge, that's
6 actually the total amount of the total fine. The counts are
7 separated at paragraph 205 by individual counts.

8 THE COURT: All right.

9 Why don't you tell me what -- help me out with what
10 the maximum fine with respect to count one is.

11 PROBATION OFFICER: It's \$209,824,000 on count
12 one. And 180 -- excuse me, \$18,400,000 on count two.

13 THE COURT: Okay.

14 PROBATION OFFICER: Thank you.

15 THE COURT: That's actually what I have.

16 Thank you.

17 Let me -- Mr. Gunning, forgive me for the
18 confusion. As I say, I don't often take pleas against
19 corporations.

20 So let me start again, and I'm going to take this
21 count by count.

22 With respect to count one, the corporation faces a
23 maximum term of probation of five years; a maximum statutory
24 fine of \$209,824; and a mandatory special assessment of \$400.

25 PROBATION OFFICER: \$209 million.

1 THE COURT: 209 -- all right.

2 Sit down, Mr. Gunning. Have a seat. I'm going to
3 try to compose myself so I can say these numbers.

4 All right. You may stand again. All right. Let
5 me do the probation first. On each count, the corporation
6 faces a term of -- a maximum term of probation of five years.

7 On each count the corporation faces a mandatory
8 special assessment of \$400.

9 On count one of the information the corporation
10 faces a maximum fine of \$209,824,000.

11 Did I say that right?

12 On count two the corporation faces a maximum fine
13 of \$18,400,000. All right?

14 Do you understand that?

15 MR. GUNNING: Very clear I understand it.

16 THE COURT: I'm certainly glad it's clear to you,
17 sir.

18 Now, before I go further, I want to ask you, sir,
19 about the total fine. The total fine is \$228,224,000, the
20 maximum fine faced by the corporation. Do you understand?

21 MR. GUNNING: Yes.

22 THE COURT: Does the corporation have the ability
23 to pay a fine of that size should it be imposed by the Court?

24 MR. GUNNING: The corporation has the ability to
25 pay.

1 THE COURT: All right. Now, there's an agreement
2 that you have that the fine that you will pay is \$136,936.
3 Since you can pay the larger am, I assume the corporation may
4 pay this smaller amount of fine; is that right?

5 MR. GUNNING: Yes.

6 THE COURT: What is the -- the corporation no
7 longer operates; is that right?

8 MR. GUNNING: The corporation continues to exist,
9 yes.

10 THE COURT: It does continue.

11 MR. GUNNING: Yes.

12 THE COURT: What would be the impact on the
13 corporation of a fine of -- first, a fine of \$228,224,000?

14 MR. GUNNING: The corporation continues to exist,
15 but will not have active operations going forward.

16 THE COURT: So the fine, if imposed, will be
17 imposed on the parent -- will be paid by the parent
18 corporation?

19 MR. GUNNING: Yes.

20 THE COURT: All right. What would be the impact on
21 the parent, that's Serono -- what's the parent corporation?

22 MR. GUNNING: The company that will pay the fine is
23 called Ares Trading.

24 THE COURT: Is what?

25 MR. GUNNING: Ares, A-r-e-s, Trading.

1 THE COURT: What's the impact on Ares Trading --
2 and by impact I mean on the net income -- over the next five
3 years of a fine of \$228,224,000?

4 MR. GUNNING: The -- I don't have the numbers
5 handy, but the fine is a very large fine. I would say it's
6 greater than the net income of the corporation for an entire
7 operating year.

8 THE COURT: The corporation meaning the defendant
9 corporation?

10 MR. GUNNING: No, I would say of the group, of
11 which the defendant is one of the affiliates.

12 THE COURT: Okay. The \$136,935,000 fine to which
13 you have agreed, what impact does that have on these
14 corporations?

15 MR. GUNNING: Your Honor, I wasn't clear. When I
16 talked about the fine, I had in my mind the complete fine both
17 on the criminal and civil side. So just referring to the 136
18 million --

19 THE COURT: Let's talk then about the fine -- first
20 I need to find out if the corporation can pay the fine. The
21 fine is 136 -- to which you've agreed -- \$136,936,000. That is
22 the fine to which you have agreed in this plea agreement. Can
23 the corporation pay that fine?

24 MR. GUNNING: Yes.

25 THE COURT: And the corporation is Serono

1 Laboratories. Can it pay the fine?

2 MR. GUNNING: Serono Laboratories -- the fine will
3 be paid by another corporation. Serono Laboratories itself
4 could not pay that fine.

5 THE COURT: And the corporation that's paying the
6 fine, what is the relationship between that corporation and
7 Serono Laboratories?

8 MR. GUNNING: It's one of the affiliated
9 corporations.

10 THE COURT: And was there a particular reason to
11 take that affiliate to pay this fine?

12 MR. GUNNING: Yes. It has the ability to pay.

13 THE COURT: Okay. And it has the ability to pay
14 \$136,936,000; is that right?

15 MR. GUNNING: It does.

16 THE COURT: What would be the effect on the
17 operation of the corporate group of the fine, just the fine on
18 the net income of the corporate income?

19 MR. GUNNING: The fine, the \$136 million in my
20 rough calculations is approximately 25 percent of the entire
21 corporate affiliated group's net income for one year.

22 THE COURT: Okay. I ask this question, just so
23 that everyone knows and I'm just not -- this is not idle
24 curiosity. I have to determine at the end of this process
25 whether I can accept the agreement that you have entered, and

1 in determining whether I can accept that agreement, I have to
2 determine whether the goals of sentencing as set forth in Title
3 18 United States Code section 3553(a) have been met. One of
4 such goals is: Is punishment sufficient in the circumstances?
5 And another goal is to deter activities in the future. And I
6 have to be certain that the punishment in this case, and I, in
7 truth, should include the entire global arrangement here, is
8 sufficient to meet these goals of sentencing.

9 So that's why I asked. So I put to you now whether
10 the corporation or one of these corporations or all of them can
11 pay the amounts to which the corporation has agreed as
12 restitution and fine, the total of some \$700 million. Can that
13 be paid?

14 MR. GUNNING: That can be paid.

15 THE COURT: The fine, as I understand it, is to be
16 paid within seven days of the judgment being entered. I think
17 it's judgment being entered; is that right? That is right,
18 Ms. Carmody?

19 MS. CARMODY: Yes, your Honor.

20 THE COURT: If I were to enter the judgment today,
21 this afternoon, could that \$136,936,000 be paid within seven
22 days of today?

23 MR. GUNNING: Yes. Our intention is to pay all
24 amounts tomorrow.

25 THE COURT: All right. And as to the remaining

1 \$500 million, how is that to be paid?

2 MR. GUNNING: The intention is to pay the entire
3 global settlement tomorrow.

4 THE COURT: Now, I ask this -- this is not
5 necessarily part of your plea, but I ask this to all of you
6 here today, counsel in particular, I understand from the papers
7 that the restitution aspect of this settlement, the \$500
8 million, largely is restitution to the Medicaid program and to
9 the states participating in the Medicaid program, and that the
10 Medicaid losses comprise 90 percent of the total losses from
11 the wrongful conduct of this corporation; is that correct,
12 Ms. Carmody?

13 MS. CARMODY: Yes, your Honor. The total -- the
14 total sales for the drug, the total reimbursement was 90
15 percent -- the total Medicaid reimbursement was 90 percent of
16 the total sales for this drug. So that there were -- medicaid
17 accounted for 80 percent of the prescriptions, but 90 percent
18 of the total sales, because Medicaid state agencies provided
19 different reimbursement rates. So, yes, you're correct, bottom
20 line is 90 percent is correct.

21 THE COURT: So the losses being reimbursed to which
22 restitution will apply will be 90 percent of the actual losses,
23 as you determine to be; is that right?

24 MS. CARMODY: Yes.

25 THE COURT: Or estimated to be.

1 MS. CARMODY: Yes, your Honor.

2 THE COURT: So that there is no -- there will be no
3 restitution in this arrangement for 10 percent of the losses as
4 estimated; is that right?

5 MS. CARMODY: That's correct, your Honor.

6 THE COURT: And those losses will have been --
7 would have been incurred by perhaps by private insurers or by
8 private individuals; is that right?

9 MS. CARMODY: That's correct, your Honor.

10 THE COURT: Now, may I ask you, all of you -- any
11 one of you can comment on it -- whether you considered in
12 putting this global settlement together the possibility -- I
13 understand that you say that there's difficulty in trying to
14 compensate everybody who may have suffered a loss, the one
15 quick thing that I learned from the memorandum that the
16 government had filed is that there may be 9,000 individuals.

17 So I ask -- and maybe this isn't a question for
18 you, Mr. Gunning, right now, but I ask the lawyers who have
19 negotiated this deal, whether there was ever a consideration
20 given to a 100 percent restitution in which the 90 percent
21 would have been distributed or allocated in the manner in which
22 you've allocated; namely, back to the Medicaid program to be
23 allocated to the various states, and ten percent put in a fund
24 to which other people who have -- other parties who have
25 suffered a loss, private insurers, individuals, could apply for

1 relief?

2 Now, that would be \$50 million or so?

3 MS. CARMODY: I don't know the math, your Honor,
4 but --

5 THE COURT: And believe me, as you have heard, math
6 is not my strong suit.

7 MS. CARMODY: Neither mine.

8 MR. GUNNING: That's about 10 percent of the civil
9 settlement, \$50 million, yes.

10 THE COURT: I did get that right?

11 MS. CARMODY: Ten percent of the civil recovery,
12 you're exactly right, your Honor.

13 THE COURT: Well -- all right. I've had my
14 probation officer sitting here to help me with these numbers.

15 All right. But the question is: Did you consider
16 putting the \$50 million, the remaining 10 percent of the loss
17 in a fund for victims to apply for relief?

18 MS. CARMODY: We did not consider that particular
19 solution to the issue that confronted us, your Honor.

20 We did give careful consideration, the government
21 did, in the context of our obligations to what we could or
22 could not do with respect to even identifying those other
23 victims.

24 There was, and continues to remain, and I think the
25 parties agree on this, an inordinate difficulty even

1 identifying who those victims would be. There are insurers
2 that did pay for the drug, private insurers.

3 To go into the facts of the case, with respect to
4 how those insurers decided and determined to reimburse and
5 whether or not those reimbursements were based on the
6 fraudulent activity of the company, we couldn't determine that
7 on an individual insurer basis. It would be impossible.
8 There's almost 1,000 insurers that we know of.

9 The factual database that we could go to to even
10 determine who those private payers were is a company document
11 called the SeroCAD database, that's a medical reimbursement
12 option that the company afforded private payers to try to
13 facilitate payment for patients. That database does not
14 identify all the payers at this point, and so we could not even
15 identify all the private payers.

16 With respect to the patients who received the drug,
17 as we said, about 85 to 90 percent of the patients who received
18 the drug were Medicaid patients. The private -- the ones that
19 had private insurance would have been -- had an opportunity to
20 receive insurance reimbursement for the drug. What the rates
21 were as between the patient and the insurance company would be
22 almost impossible to determine. Each insurance company had a
23 difficult -- a different way to -- in different terms of the
24 contract to determine how much a patient was required to pay
25 versus the insurance company.

1 So that's a very difficult thing to determine.

2 In addition, there were patients that paid cash for
3 this drug, and so that there are patients out there that did
4 pay out-of-pocket for the drug, no question.

5 It's impossible for us to determine who those
6 patients were for a number of reasons, including a lack of
7 complete database from the company records, as well as there's
8 no insurer or Medicaid agency that would have a record of these
9 individuals.

10 There was a program by the company that provided
11 some free drug to patients, and so that there were patients
12 that received drugs from the company that way.

13 So in terms of the total complex picture here, we
14 were not able to determine even with respect to reimbursement
15 rates or the fraudulent activity what we could attribute to
16 those private payers; and with respect to the individuals, it's
17 an almost impossible task to even identify them.

18 Did we consider the option that the Court just
19 mentioned in terms of the total construct of the settlement?
20 No, your Honor, we did not.

21 THE COURT: Well, let me -- maybe the question goes
22 beyond did you consider. Wouldn't it be possible to take this
23 \$50 million and announce to the public that there is a fund of
24 \$50 million and that fund is being held for people who may
25 be -- for parties who may be victims of this scheme to which

1 the corporation is pleading, or these schemes; and the people
2 who believe they have claims, the parties who believe they have
3 claims would go to some arbiter, mediator -- I'm thinking of a
4 9/11 program.

5 MS. CARMODY: Right.

6 THE COURT: And they would present their claims to
7 that person, and that person would decide the validity of the
8 claim, how much of it -- of that \$50 million should go to any
9 given party, and so on. And I particularly have in mind the
10 individuals that you spoke of who might have paid out of their
11 pocket.

12 The private insurers, if they think they have been
13 defrauded, could also apply, but they also have more
14 substantial means to take on this company themselves, but I
15 have in mind in particular individuals who may have paid
16 out-of-pocket or individuals who may have paid not all of it
17 out-of-pocket but whatever deductible amount or co-insurance
18 amount they had to pay either Medicaid or private insurer was
19 paying the principal amount.

20 I understand we're talking \$7,000 a week or
21 something like that.

22 MS. CARMODY: Yes, your Honor.

23 THE COURT: So if a particular person using this
24 drug had to pay \$7,000 a week for X number of weeks and had
25 co-insurance, let's say 10 percent, we're talking that person

1 having lost \$700 a week, and those -- that person in this
2 settlement is never going to be reimbursed or no attempt would
3 be made to reimburse that person or give restitution to that
4 person. And that -- I'm stuck on that, I have to tell you.

5 MS. CARMODY: Your Honor, I understand where the
6 Court's coming from; and if we thought that that was a workable
7 solution, I would be the first proponent for it.

8 In order to do that, the government would have to
9 fund a program --

10 THE COURT: Why does the government have to do
11 that? Why can't the defendant do it?

12 MS. CARMODY: Serono would have to do it. In the
13 context of this case I guess they would.

14 To set it up, to set up -- put somebody in charge
15 of it, you'd have to hire somebody --

16 THE COURT: I understand.

17 MS. CARMODY: You'd have set criteria, you'd have
18 to have investigation to know in fact whether or not the claims
19 that were made against the fund were proper and not
20 fraudulent. It's the kind -- it's exactly the kind of huge
21 complication that the statute, I think, looks to to say if it's
22 that complex -- if we were to try to have done that, your
23 Honor, we wouldn't be here today, we'd still be out talking
24 about how to get that done.

25 It took over -- it took four years of investigation

1 and over a year of just negotiation not just with the federal
2 government, but all of the 50 states and the District of
3 Columbia. So that in order to effectuate this global
4 resolution, the company not only had to negotiate with the
5 federal government, each one of the states have a separate
6 civil settlement agreement so that each of the 50 states had to
7 sign on to the settlement agreement.

8 The primary goal of the statutes that we're
9 prosecuting, not that -- and I'm not in any way looking away
10 from any patient victims or insurer victims, but the primary
11 goal of our statute is to make the government --

12 THE COURT: I understand.

13 MS. CARMODY: -- and its states whole.

14 THE COURT: I understand.

15 MS. CARMODY: So I think that the kind of
16 well-intentioned program that the Court has described I think
17 it's simply something that is so complex that it would be
18 impossible to effectuate in the context of this negotiation in
19 this plea.

20 THE COURT: Well, you don't mean impossible; you
21 mean difficult, don't you?

22 MS. CARMODY: Extraordinarily difficult.

23 MR. GUNNING: If I could --

24 THE COURT: It could be done; it has been done.

25 Yes, sir.

1 MR. GUNNING: Just one thing to add in terms of
2 your concern about the individuals who paid. Again, I don't
3 have numbers, but I have the firm understanding that the cash
4 paid by individuals for the product is a very, very small
5 percentage of even that ten percent remainder.

6 THE COURT: Okay.

7 Well, I hear what Ms. Carmody has said, and I
8 hear -- I interpret what she has said to mean that this
9 settlement represents the greatest good for the greatest
10 number.

11 MS. CARMODY: Yes, your Honor; I would say that.

12 THE COURT: And that if I wanted to engraft some
13 other condition on this settlement -- of course you'd be
14 allowed to withdraw your plea, and you might decide not to
15 plead to anything and the whole thing would go down the tube,
16 that could happen; is that right?

17 So I have to think about whether I want to insist
18 on that, what happened to that \$50 million, as against all of
19 the complications of negotiating with the company -- the United
20 States negotiating with the company and then negotiating with
21 all the 50 states.

22 I want to think about that just for at least a few
23 minutes, because I just want to ask for the company's point of
24 view, the corporation's point of view.

25 I recognize this is a difficult administration

1 matter, but in the context of the settlement as a whole, this
2 is a relatively small amount of money, \$50 million, and I am,
3 as you heard me say, concerned about the individual --
4 concerned about the private insurers as well, but I have the
5 notion that the private insurers are better able to protect
6 themselves than private individuals.

7 You say that there aren't very many of such people
8 or if there are very many of such people, they didn't pay much
9 money, Mr. Gunning. Is that what you said?

10 MR. GUNNING: That's my understanding. That if
11 there is -- in terms of actual cash patients paying for the
12 product, that it is less than one percent of what was paid for
13 the product.

14 THE COURT: Okay. Well, I have in mind the
15 scenario where there are especially vulnerable victims at the
16 end of this chain. You don't -- the guidelines -- sentencing
17 guidelines don't permit the kind of ratcheting up of the
18 punishment in this kind of case for a specially vulnerable
19 victim, but there are especially vulnerable victims who are
20 people who have AIDS; and as I understand what has happened,
21 what the government charges and what the corporation is
22 planning to plead guilty to, is the selling of devices and
23 medication to these victims with the promotion by the
24 corporation that a symptom of their illness was wasting of the
25 body; and that even in cases where they may not have had that

1 symptom, they were led to believe that they did have that
2 indication, that they were suffering, and they paid for the
3 medication, they paid for the devices, which means to me that
4 the person who pays -- who might have paid \$700, ten percent of
5 a private insurer, puts the \$700 down as his or her
6 co-insurance, and that \$700 can't be used to buy something
7 else, other medication or pay the rent, pay the mortgage
8 because it's going into the payment of -- for this device and
9 this medication, which the patient had been led to believe is
10 necessary for his health when it was not.

11 And so I don't want to preach about this, but I am
12 concerned about those people who had to pay the \$700, and maybe
13 there are a few and who made choices that they didn't have to
14 make.

15 Now, I just need -- at the end of the day you'll
16 have to talk to me again about those people.

17 I understand the global nature, I understand this
18 is the greatest good, but I -- between the United States, the
19 corporation. I see my role is to sort of speak for the
20 individual who has suffered that particular harm. And maybe at
21 the end of the day this will be all right, this settlement is
22 all right because it is the greatest good for the greatest
23 number. And I don't want to mess it up so that that great good
24 cannot be achieved, because at the end of the day what I hear
25 is that the compensation is going to go to us as tax -- the

1 taxpayers, all of us individual will get our money back; but
2 the person who won't get their money back is that person who
3 paid the \$700 co-insurance.

4 All right. I'm through with the sermon about that,
5 but I want to come back to it, because you have to satisfy me
6 that I need to accept this plea knowing that there is X and Y
7 and Z out there who spent \$700. And maybe they didn't take the
8 cocktail, who maybe got worse, and if not physically worse,
9 psychologically worse because of this activity.

10 All right. Let me move on, because I haven't done
11 this, but let me move on.

12 Okay. Now, Mr. Gunning, let me make sure you
13 understand that the corporation does not have to plead guilty.
14 The corporation can plead not guilty and is entitled to a trial
15 by jury, which the corporation is entitled to the assistance of
16 counsel. It would have a right in a trial to confront the
17 witnesses against the corporation and have those witnesses
18 examined in the defense of the corporation. The corporation
19 would have the right to testify, to call witnesses on its own.
20 If the corporation wanted to call witnesses and those witnesses
21 were reluctant to come to court, the corporation would have the
22 right to have the court issue subpoenas for those witnesses
23 appear.

24 On the other hand, the corporation has the absolute
25 right, guaranteed by the fifth amendment of the Constitution,

1 to put the government to its burden of proof. The corporation
2 would have no burden at trial; and, therefore, the corporation
3 would not have to put on a defense, would not have to call any
4 witnesses, and would not have to testify on its behalf. That
5 if the corporation took that course, I would instruct the jury
6 in the strongest possible terms that no inference of guilt or
7 anything else and no -- well, let me leave it at no inference
8 of guilt or anything else could be drawn by the jury because
9 the corporation decided not to offer a defense.

10 I guess what I usually say is that the jury would
11 be -- could not hold it against the corporation if it offered
12 no defense or had no one testify on its behalf.

13 And I would tell you, as I would tell any
14 individual before me, that before I seated any jury in this
15 case I would inquire of the potential members of the jury, each
16 of them, whether any one juror would hold it against the
17 corporation or draw an inference adverse to the corporation
18 because the corporation did not testify or otherwise present a
19 defense.

20 If some potential juror indicated to me that that
21 juror would hold it against the corporation or draw an
22 inference adverse to the corporation if the corporation didn't
23 testify or offer a defense, I would not seat that person.

24 I try to challenge that by asking potential jurors
25 if they think that the corporation must be guilty otherwise the

1 corporation wouldn't be in the courtroom charged with two
2 felonies.

3 And if some potential juror were to indicate in
4 some fashion, however remote, that he or she harbored that
5 feeling, I wouldn't seat that person.

6 Now, if the corporation pleads guilty, all the
7 rights that I've just explained and all the rights that are
8 associated with a trial by jury in this court in a felony
9 criminal case will have been waived.

10 Does the corporation understand that?

11 MR. GUNNING: Yes.

12 THE COURT: Has the corporation's decision to plead
13 guilty in this case resulted from discussions between your
14 attorneys representing the corporation and the attorneys for
15 the government?

16 MR. GUNNING: Yes.

17 THE COURT: Is the plea of guilty that you propose
18 to make on behalf of the corporation a voluntary plea because
19 the company, the corporation is guilty of these offenses?

20 MR. GUNNING: Yes.

21 THE COURT: Let me advise you that at trial, as I
22 think I've said or at least suggested, the burden would be upon
23 the United States to prove the corporation guilty of these
24 offenses, and the burden upon the United States is to prove the
25 corporation's guilty by proof beyond a reasonable doubt. That

1 means, Mr. Gunning, that with respect to each of these two
2 counts, the government must prove each of the separate things
3 that make up the offense charged in that count by proof beyond
4 a reasonable doubt. The failure of the government to prove the
5 separate things that make up an offense against the United
6 States are called the elements of that offense. The failure of
7 the government to prove even one element, even if it proves all
8 the others save one, means that the corporation would be
9 entitled to a verdict of not guilty.

10 Now, with respect to count one of the information,
11 the government must prove the following elements: First, that
12 there was a conspiracy among at least two persons to introduce
13 into interstate commerce, with intent to defraud or mislead,
14 adulterated medical devices as charged in the information; that
15 at sometime during the life of that conspiracy the corporation,
16 understanding what the conspiracy was all about, deliberately
17 and intentionally joined that conspiracy and intended by
18 joining that conspiracy to advance the purposes of the
19 conspiracy.

20 And, finally, the government must establish that at
21 sometime during the life of the conspiracy and during a time in
22 which the corporation was a part of it, one of the
23 conspirators -- I'm sorry, I don't -- let me revise this last
24 statement.

25 Sometime during the life of the conspiracy some

1 member of the conspiracy committed some overt act for the
2 purpose of advancing the conspiracy.

3 Do you understand?

4 MR. GUNNING: Yes.

5 THE COURT: With respect to count two, which also
6 charges conspiracy, this conspiracy also is charged under Title
7 18 United States Code section 371, this is a conspiracy charged
8 in the information as one to offer to pay illegal remuneration
9 to health care providers. In that case, the government must
10 prove that there was a conspiracy among two or more persons to
11 offer to pay illegal remuneration to health care providers;
12 second, at sometime during the life of that conspiracy, the
13 corporation, understanding what the conspiracy was all about,
14 joined intentionally deliberately with the intention by joining
15 to advance the purposes of the conspiracy; and third, that at
16 sometime during the life of that conspiracy one of the
17 conspirators committed an overt act to advance the purposes of
18 the conspiracy.

19 Do you understand, sir?

20 MR. GUNNING: Yes.

21 THE COURT: Mr. Gunning, do you have any question
22 you want to ask me before you go any further?

23 MR. GUNNING: No.

24 THE COURT: You hesitated, so if you have a
25 question, this is the time to ask.

1 MR. GUNNING: No, I guess as you go through -- I
2 understand the elements, and I believe that there are facts
3 that are sufficient to show those elements; but we don't agree
4 with all of the facts that are set forth in the information or
5 the sentencing memo. So that was the reason for my hesitation.

6 THE COURT: All right. Well, let me do this: Is
7 the government prepared to make a representation of what it
8 would show if the case were to go to trial?

9 MS. CARMODY: Yes, your Honor, we are.

10 THE COURT: Have a seat, Mr. Gunning. Listen
11 carefully as Ms. Carmody summarizes the case the government
12 would present if the case were to go to trial.

13 MS. CARMODY: Your Honor, if the case were to go to
14 trial, the evidence would show the following -- and I'm going
15 to incorporate by reference the government's sentencing
16 memorandum, which was filed yesterday; and if there is any fact
17 or point that I don't -- I fail to mention here because it's so
18 complicated, I would refer back to the sentencing memorandum.

19 THE COURT: The defendant has that sentencing
20 memorandum?

21 MS. CARMODY: Yes, your Honor.

22 THE COURT: Okay.

23 MS. CARMODY: The two conspiracies charged in the
24 information are components -- are two components of an illegal
25 marketing scheme by the defendant Serono Labs and others to

1 increase the sales offer, which is a form of recombinant human
2 growth hormone approved by the FDA for AIDS wasting, a
3 condition characterized by profound involuntary weight loss in
4 AIDS patients.

5 Beginning in August of 1996, the FDA initially
6 granted accelerated approval for Serostim for the condition of
7 wasting, which was at that time an AIDS defining condition and
8 a leading cause of death among those effected by HIV and AIDS.

9 Shortly following the launch of Serostim in the
10 fall of 1996, the incidence of AIDS wasting began to decline
11 markedly as a result of the simultaneous advent of protease
12 inhibitor drugs administered with other drugs in various
13 cocktail combinations commonly referred to as Highly Active
14 Anti-Retroviral Therapy, or HAART, H-A-A-R-T. The HAART
15 regimens treated the HIV virus itself, and, as a result,
16 averted the condition of wasting, which the drug Serostim was
17 developed to treat.

18 Consequently, many physicians declined to prescribe
19 Serostim, because it was not medically necessary and it was
20 also a very expensive drug, approximately costing \$21,000 for a
21 12-week course of therapy.

22 Confronted with the rapidly diminishing market,
23 Serono Labs and others embarked on a campaign to redefine AIDS
24 wasting immediately following that launch. The company sought
25 to expand the definition of AIDS wasting to encompass newly

1 emerging symptoms exhibited by AIDS patients and promoting
2 Serostim to treat these symptoms --

3 THE COURT: You're beginning to speed up again.

4 MS. CARMODY: I'm sorry, your Honor.

5 THE COURT: Keep it, you know, in a more
6 conversational pace so we can all understand.

7 MS. CARMODY: Sure, your Honor.

8 THE COURT: You were telling me that the company
9 began a campaign to redefine AIDS wasting.

10 MS. CARMODY: AIDS wasting.

11 THE COURT: AIDS wasting.

12 MS. CARMODY: They sought to expand the definition
13 of AIDS wasting to encompass newly emerging symptoms that were
14 not symptoms or conditions for which the drug was granted
15 approval by the FDA.

16 Principally, and this refers to specifically count
17 one of the indictment, Serono Labs began using what's called
18 the bioelectrical impedance analysis, or BIA testing device,
19 which was a medical device that the company used to,
20 quote-unquote, unmask wasting. And they also, referring to
21 count two, offered illegal remunerations, offered to pay or did
22 pay for doctors an all-expenses paid trip to a medical
23 conference in Cannes, France, which I'll refer to as the Cannes
24 conference.

25 The conspiracy to disseminate the BIA device began

1 in 1996 and lasted at least through 2002.

2 Serono Labs knowingly and willingly conspired with
3 the medical device maker RJL Sciences, Inc., which was a
4 company that was run by a person named Rudy Liedtke and is
5 located in Michigan. RJL Sciences was the one to develop the
6 BIA device, the testing device as well as the accompanying
7 software, which are a separate medical device, and which were
8 the adulterated devices that I referred in count one of the
9 information.

10 Despite knowing that the FDA did not approve the
11 medical device for use in diagnosing AIDS wasting or to
12 diagnose a condition -- to be used as a device to determine
13 whether a patient was suffering from a condition known as body
14 cell mass wasting, both Serono and RJL agreed to disseminate
15 that device to both patients and other providers with respect
16 to those who were treating or providing for AIDS patients so
17 that that device could be used to diagnose the condition called
18 AIDS wasting.

19 Serono Labs used an array of practices to
20 manipulate the BIA testing device. And the BIA testing device
21 was basically a very small device with electrical cords that
22 extended from it that were put on the hands and feet of
23 patients. And the purpose of -- when they put it on the
24 patient was to measure the electrical current rubbing through
25 the patient to determine the resistance and the reactants.

1 Those two measurements were taken -- which were
2 determined by the testing device, had to be taken manually from
3 the device and inserted into a computer system and operated
4 through a computer software in order to determine whether or
5 not a patient -- what the measurements were, for among other
6 things, body cell mass.

7 THE COURT: May I ask you something as you go
8 along? Because this isn't very -- has never been clear to me.

9 Does this device, this BIA device have value at
10 all? Or is what you're saying it does something that is useful
11 but the results were manipulated?

12 MS. CARMODY: It's originally -- its original use,
13 your Honor, was for nutritional purposes to determine body
14 composition. And people that -- particularly people that have
15 weight loss problems or people who want to bodybuild or other
16 people who are particularly interested not just in what their
17 weight is on a scale, but what is the composition of elements
18 within one's body, that makes a difference in terms of how the
19 weight is both distributed in the body and how it works within
20 the body.

21 So the original purpose, which was developed by the
22 company in the 1980s, was to just determine a person's body
23 composition for nutritional purposes.

24 The use that brought it forward into diagnosing a
25 medical condition, that was a use -- that's exactly the use

1 that was not approved by the FDA in this case and was not
2 specifically approved for diagnosing AIDS wasting.

3 So did it have any actual benefit to patients other
4 than attempting to diagnose AIDS wasting? For these purposes,
5 no, your Honor.

6 THE COURT: Did it not diagnose AIDS wasting -- did
7 it diagnose AIDS wasting as redefined?

8 MS. CARMODY: As redefined.

9 THE COURT: And the software packages that went
10 into the program were designed -- were fraudulent altogether or
11 were the results manipulated? It's something that wasn't clear
12 to me.

13 MS. CARMODY: Both, your Honor.

14 THE COURT: Okay.

15 MS. CARMODY: What happened was that in -- when the
16 company knew that they were losing -- basically, to define --
17 AIDS wasting is a condition that you can see immediately. In
18 the 1980s and the early '90s when people were suffering from
19 HIV and AIDS, you can see the gaunt look, the holocaust
20 survivor look, and that's AIDS wasting; you can measure that on
21 a scale.

22 You can measure --

23 THE COURT: You mean a regular bathroom scale?

24 MS. CARMODY: Right. Because the question was
25 whether these patients had an intentional weight loss of more

1 than ten percent or preferential weight loss of lean body mass
2 over fat, so that people were losing the stuff that really held
3 your body together and made it healthy, organs and that sort of
4 thing.

5 So that when the company knew that they didn't have
6 that quantity of patients that had lost more than ten percent
7 of their weight loss or more than 90 -- or were lower than 90
8 percent of ideal body weight, and it was an unintentional
9 weight loss -- people can lose weight for a lot of different
10 reasons that have nothing to do with this specific issue,
11 people can lose weight because they have a form of cancer or
12 they have an infection or they're not eating right. This is
13 unintentional weight loss. So people that are losing weight,
14 don't want to, and can't figure out why they're doing that. So
15 that was one issue.

16 But when the protease inhibitors came on the market
17 in the late 1990s -- 1996, just at the same time, they treated
18 the virus itself, the HIV virus itself, which then resulted in
19 that wasting condition essentially declining and almost
20 disappearing. Although there is a small percentage of patients
21 even today that are resistant to those drugs or for some other
22 reason do not respond to the HAART cocktail; and, therefore, a
23 small patient population for whom this can be a life saving
24 drug.

25 THE COURT: So the software that the company

1 developed would work for these folks, the people who -- who --
2 for whom the protease inhibitors will not work? Will it really
3 work to give them useful information? Or is it simply the
4 software is just a sham?

5 MS. CARMODY: It's a sham, your Honor. It was
6 always a sham.

7 The patients that really need the drug were very
8 easy to diagnose, and the company in its documents describe
9 patients as severe wasting, body cell mass wasting, and the --
10 and so that they made clear distinctions between a patient with
11 severe wasting and body cell mass wasting.

12 Body cell mass wasting could only be diagnosed
13 using the BIA machine and was never recognized in any respect
14 by the FDA, either as an appropriate criteria for the patient
15 population on whom this drug was tested in the FDA process of
16 the approval process, both pre -- before receiving accelerated
17 approval, and in the phase four confirmatory trials. The FDA
18 never recognized that as a valid criteria for determining
19 whether or not Serostim was either safe or efficacious.

20 So that criteria was never within the contemplation
21 of the FDA in putting this drug on the market.

22 (Discussion off the record.)

23 MS. CARMODY: And with respect to going beyond that
24 condition which doctors could readily diagnose and see, the
25 only way to expand the definition of the disease state was to